



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 14, 2020

Sara Seltzer
Registration Specialist
Diversey, Inc.
2415 Cascade Pointe Boulevard
Charlotte, NC 28208

Subject: Label Amendment – Emerging Viral Pathogens Claim
Product Name: Avert Sporocidal Disinfectant Cleaner Wipes
EPA Registration Number: 70627-75
Application Date: March 11, 2020
Decision Number: 560812

Dear Ms. Seltzer:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

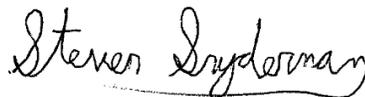
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, or enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus (ATCC VR-782) and Canine Parvovirus (ATCC VR-2017) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact disinfectants list at disinfectantslist@epa.gov.

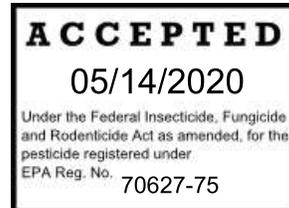
Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

(Note to Agency: Text appearing in parenthesis is done to show optional text.)



Avert Sporicidal Disinfectant Cleaner Wipes

(For Institutional Use)

(Kills C. Diff spores(!))

| | |
|---------------------------------|----------|
| ACTIVE INGREDIENT: | |
| Sodium hypochlorite | 1.312% |
| OTHER INGREDIENTS: | 98.688% |
| TOTAL: | 100.000% |

1.25% available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER**

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center for treatment advice.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR FURTHER TREATMENT ADVICE.

(Note to Reviewer: Working Emergency Number Will be Printed Here)

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

[See additional precautionary statements on back (side) (left) (right) (panel) (of) (label) (below).]

(Keep container (package) tightly sealed when not in use.)

[Note to Reviewer: This statement will appear on the product label until the twelve month storage stability is complete and accepted by the Agency.]

Not for sale or use on or after [insert date].

Net Contents:

[Made in (Product of) _____]

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(CLAIMS:)

(Marketing Statements:)

- A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces
 - Always Ready-to-Use
 - Antibacterial cell phone wipe
 - Bleach-based formula means no quat-binding concerns
 - Disposable
 - Each pre-moistened (disposable) towelette (wipe) cleans, deodorizes and kills listed bacteria all around your (hospital) (office) (business) (workplace)
 - Easy flip-top lid
 - Eliminates buckets
 - Great for on-the-go cleaning
 - Great on-the-go disinfectant (towelette) (wipe)
 - Just pull, wipe & toss!
 - No measuring or mixing required
 - No need to Spray!
 - Non-woven disposable (towelette) (wipe)
 - On-the-go disinfectant
 - Pre-measured
 - Pre-moistened (towelettes) (wipes)
 - Pre-soaked (towelettes) (wipes)
 - Quick and easy cleaning everywhere
 - Ready to Use (Easy to Use) (Towelettes) (Wipes)
 - Restroom (disinfectant) wipes (for hard, non-porous surfaces)
 - Stay-moist package
 - Strong towelettes (wipes)
 - Telephone (cleaner) (and) (disinfectant) wipes
 - These wipes are a convenient way to disinfect surfaces all around your (hospital) (business) (office) (workplace)
 - Wipe down grocery (or shopping) cart handles
-
- (A heavy duty disinfectant cleaner that) Cleans, disinfects, and deodorizes in one labor saving step.
 - Cleans (Cleaner), (and) Deodorizes (Deodorant) (Deodorizer), Disinfects (Disinfectant), *Virucidal (*Virucide), Fungicidal (Fungicide)
 - Cleans everyday messes
 - Contains 12,500 ppm of (chlorine) (Contains 12,500 ppm of sodium hypochlorite)
 - Convenient
 - (Designed) For daily use (Use for) daily (or) (discharge) (cleaning) (in Healthcare)
 - Does not require (the hassle of) dispensing systems

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

- Efficient. Cuts cleaning time.
- Fragrance-free
- Makes cleaning easier
- Multi-surface cleaner disinfectant
- No added (perfume) (fragrance) (and) (or) (dye)
- No harsh (alcohol) (vinegar) (and) (or) (peracetic acid) smell
- Non-abrasive (formula) (product)
- Recyclable (bottle) (product container)
- The smell of clean
- Will not leave grit or soap scum on surfaces

This product (These) (are) (is) (a) non-woven, disposable (towelette(s)) (wipe(s)), pre-saturated with disinfectant cleaner. This product (It) cleans, disinfects, and deodorizes hard, nonporous inanimate (environmental) surfaces (and patient care equipment) in one step with no rinsing required (after use). This product is a (one-step,) (broad spectrum,) (hospital,) disinfectant (germicidal) cleaner and deodorizer (odor counteractant) designed for general cleaning, disinfection and deodorizing of hard, nonporous surfaces. (Designed for (non-critical) hard, nonporous surfaces in healthcare.) (It quickly) Removes (bathtub ring,) blood, body fluids, dirt, fungus, food residue, fecal matter, grime, laboratory stains, soils, stains, urine and other organic matter commonly found (on hard, nonporous, inanimate (environmental) surfaces) (patient care equipment)) (in hospitals and healthcare facilities) (where housekeeping is of prime importance in controlling the hazard of cross-contamination). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(This product can be used) (Use) in the following areas:

(Medical Facilities:)

- alternative care facilities,
- ambulances or (emergency medical) transport vehicles,
- ambulatory care centers (ASCs); ambulatory surgery centers,
- anesthesia rooms,
- assisted living facilities,
- CAT laboratories,
- central service areas,
- central supply rooms,
- clinics,
- critical care units,
- dental clinics (offices),
- examination (exam) rooms (areas),
- emergency rooms (ERs) (areas),
- dialysis clinics (facilities),
- (blood) (plasma) donation centers,
- eye surgical centers,
- home health care (settings),
- hospices,
- hospitals,
- (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs),
- isolation rooms (areas),
- laboratories,
- laundry rooms,
- long-term care facilities (homes),
- medical facilities,
- (medical) (physicians') (doctors') offices,
- (neonatal) (newborn) nurseries,
- nursing homes,
- operating rooms (theaters),
- ophthalmic offices,
- outpatient (surgical) centers (clinics) (OPSCs) (facilities),
- patient rooms,
- (physical) (patient) therapy rooms,
- procedure rooms,
- psychiatric facilities,
- radiology (X-Ray) rooms (areas),
- reception areas,
- recovery rooms,
- rehabilitation centers,
- skilled nursing facilities,
- surgery rooms,
- waiting rooms (areas).

(General Institutional Facilities:)

(Cross-contamination is a major Infection Prevention concern.) (This product has been developed to aid in the reduction of cross-contamination on treated surfaces (not only in hospitals (and healthcare facilities), but also) in:)

- airports,
- animal hospitals,
- animal housing facilities,
- animal treatment facilities,
- animal life science laboratories,
- athletic facilities,
- bathrooms,
- bus (depots) (stations),
- casinos,
- correctional facilities,
- cruise ships,
- food service,
- funeral homes,
- health clubs,
- hotels (motels),
- institutions,
- locker rooms,
- office buildings,
- pet shops,
- playgrounds,
- public buildings,
- public restrooms,
- recreational facilities,
- retail businesses,
- schools (colleges, and universities),
- train (depots) (stations),
- transportation terminals (facilities),
- veterinary clinics.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(It is designed) For (daily) (use) (cleaning) (disinfecting) (on) (of) (medical) hard, nonporous inanimate (environmental) surfaces (materials) (Compatible with): acrylic, baked enamel surfaces, Corian[®], glass, glazed ceramic (tile), glazed porcelain, glazed tile, laminated surfaces, sealed mirror stone, painted surfaces, plastic (surfaces), quarry tiles, sealed granite, sealed marble, stainless steel, finished terrazzo and vinyl.

Not recommended for use on (or) (avoid contact with): aluminum, brass, chipped enamel, clear plastic, copper, finished floors, natural marble, painted surfaces, and silver. (Not for use on soft, porous surfaces such as clothing, fabrics, textiles, paper surfaces, and unfinished wood.)

Note: This product is compatible with the listed materials. If product is intended to be used on other surfaces, it is recommended to test product by applying to a small discrete area to determine compatibility before proceeding with its use.

This product cleans, disinfects and deodorizes (common) hard, nonporous (hospital) (non-critical) (semi-critical) (medical) surfaces (patient care equipment) in one step (with no rinsing required). (Designed for (daily) use on (common) hard, nonporous (materials) (inanimate) (environmental) surfaces (patient care equipment) found in hospitals and other healthcare facilities.) (May be used to clean and disinfect sinks, faucets, fixtures, bathrooms, restrooms, tubs, and showers.) (For non-scratch cleaning of showers, tubs, shower doors and nonporous curtains, and fixtures, urinals, and exterior surfaces of toilets.) It can be used on the following:

(Medical Surfaces/Items:)

[Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, it can be used to disinfectant the following noncritical medical items:]

- exterior surfaces of autoclaves,
- backboards,
- (hospital) (patient) beds, bedrails, bedframes, bed springs,
- bedpans,
- bedside (overbed) tables,
- blood pressure cuffs,
- blood pressure monitors,
- cabinets,
- call buttons (boxes),
- (crash) (medication) carts,
- computerized axial tomography equipment (CATs),
- chemotherapy hoods,
- cellular phones,
- chairs,
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- remote (portable) controls (controllers),
- counters (countertops),
- desktops,
- diagnostic equipment,
- exterior surfaces of dialysis machines,
- docking stations,
- doors,
- exterior surfaces of (medical) equipment,
- faucets,
- fixtures,
- footboards,
- exterior of glucometers,
- gurneys,

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

- handheld electronic devices,
- handles,
- headboards,
- high touch surfaces,
- isolettes,
- IV stands (poles) and exterior surfaces of pumps,
- laptops,
- loupes,
- mammography equipment,
- exterior surfaces of magnetic resonance imaging equipment (MRIs),
- mobile devices (electronic equipment),
- mobile workstations,
- operating room tables, (lights,) (light switches,) (wall mounted controls),
- (and exterior surfaces of equipment,)
- orthopedics,
- pagers,
- patient care (monitoring) equipment,
- patient support and delivery equipment,
- phlebotomy trays,
- phones, phone cradles and phone accessories,
- (hard, nonporous) edges of privacy curtains,
- pulse oximeters,
- scales,
- sequential compression devices,
- side rails,
- sinks,
- slit lamps,
- (mayo) (instrument) (ring) stands,
- stethoscopes,
- stools,
- stretchers,
- support bars,
- tables, (exam tables),
- tablet PCs,
- telephones,
- exterior surfaces of toilets, (portable toilets,)
- toilet grab bars (handholds),
- traction devices and patient slings,
- exterior surfaces of (PVC) (equipment) tubing,
- urinals,
- walls,
- wash basins,
- wheelchairs,
- weighing devices/equipment,
- X-Ray equipment.

[Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, it can be used to pre-clean and/or disinfectant the following semi-critical items prior to terminal sterilization:]

- anesthesia equipment,
- respirators, respiratory equipment, respiratory therapy equipment,
- ultrasound transducers (and/or probes).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(General Surfaces Items:)

- exterior surfaces of air vents covers,
- cabinets,
- cages,
- chairs,
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- counters (countertops),
- desktops,
- docking stations,
- doors,
- exercise equipment,
- faucets,
- feeding and watering equipment,
- fixtures,
- floors (flooring),
- grocery carts,
- handheld electronic devices,
- handles,
- high touch surfaces,
- kennel runs,
- laptops,
- mobile devices (electronic equipment),
- mobile workstations,
- pagers,
- phones, phone cradles and accessories,
- sinks,
- shopping carts,
- stools,
- tables,
- tablet PCs,
- telephones,
- tubs,
- exterior surfaces of toilets,
- urinals,
- walls,
- wash basins

(found in (health care facilities) (and) (hospitals).) Do not use on glasses, dishes and utensils. In addition, this product will deodorize those areas that are generally hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, and any other areas that are prone to odors caused by microorganisms. (Disinfects, cleans, and deodorizes hard, nonporous surfaces in (restrooms,) (bathrooms,) (toilet areas,) (finished nonporous surfaces behind and under sinks and counters,) (garbage cans and garbage storage areas), and other places where bacterial growth can cause malodors.)

Note: Prior to use on electronic equipment or components, (please) refer to manufacturer's instructions (for appropriate use).

(Clostridium difficile efficacy statements:)

- Effective in 4 minutes against Clostridium difficile (C. diff) (C. difficile) spores.
- Broad spectrum (Proven) disinfectant (bactericide, *virucide, fungicide) with efficacy against Clostridium difficile (C. diff) (C. difficile) spores.
- Effective disinfectant cleaner (and Clostridium difficile sporicide) (for use in hospitals, ambulatory care centers, long term care facilities, and other healthcare facilities.)
- May be used as part of a comprehensive approach to Clostridium difficile (C. diff) (C. difficile) spore control.
- Designed for (killing) (controlling) (eliminating) Clostridium difficile (C. diff) (C. difficile) spores (on hard nonporous surfaces (and patient care equipment)) in hospitals (and other healthcare facilities).
- Effective (for daily use) against *[insert any organism from list of organisms on this label]* (multi-drug resistant organisms) (MDROs) (and Clostridium difficile (C. diff) (C. difficile) spores).
- Daily use product with (Clostridium difficile) (C. diff) (C. difficile) sporicidal efficacy which allows for product standardization (reduces (reducing) cleaning complexity) (reduces the number of products needed) (eliminates the need for a separate sporicide).
- Daily defense against (Tough on) Clostridium difficile (C. diff) (C. difficile) spores.
- Kills Clostridium difficile (C. diff) (C. difficile) spores in 4 minutes. Sporicidal against (Clostridium difficile) (C. diff) (C. difficile) spores

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(CLAIMS:)

Using approved Standard Quantitative Disk Carrier Test Method (under Good Laboratory Practices, [GLPs]), in the presence of soil and 4 (four) minute contact time, this product kills (and) (inactivates) spores of *Clostridium difficile* (ATCC 43598) on hard, nonporous surfaces.

(When used as directed, this product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic-resistant bacteria, *viruses, and fungi.) Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% serum load and 1 (one) minute contact time, this product kills the following on hard nonporous (inanimate) (environmental) surfaces:

Bacteria (Bactericidal Activity):

Pseudomonas aeruginosa, (ATCC 15442)
Staphylococcus aureus, (ATCC 6538)
Salmonella enterica, (ATCC 10708)

Campylobacter jejuni, (ATCC 29428)
Escherichia coli, (ATCC 11229)
Escherichia coli O157:H7, (ATCC 35150)

Listeria monocytogenes, (ATCC 19117)
Stenotrophomonas maltophilia, (ATCC 25596)
Streptococcus pyogenes, (ATCC 19615)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity):

Acinetobacter baumannii, Multi-Drug Resistant (MDRO) (ATCC 19606)
Enterobacter aerogenes, Multi-Drug Resistant (MDRO) (ATCC 29751)

Escherichia coli, Extended-Spectrum Beta-lactamase (ESBL) producing (ATCC BAA-196)
Klebsiella pneumoniae, Carbapenem Resistant (CRKP) (ATCC BAA-1705)

Klebsiella pneumoniae, NDM-1 positive (CDC 1000527)
Pseudomonas aeruginosa, Multi-Drug Resistant Metallo-beta lactamase (MBL) positive (CDC 2012059)

Enterococcus faecalis, Vancomycin Resistant (VRE) (ATCC 51575)

Klebsiella pneumoniae, Extended-Spectrum Beta-lactamase (ESBL) producing (ATCC 700603)

Staphylococcus aureus, Methicillin Resistant (MRSA) (ATCC 33592)

Enterococcus faecium, Multi-Drug Resistant (ATCC 51559)

Klebsiella pneumoniae, Multi Drug Resistant (ATCC 51503)

Staphylococcus aureus, Community Acquired Methicillin Resistant (CA-MRSA) Genotype USA 300, (NRS 384)

Escherichia coli, Carbapenem Resistant (CRE) (CDC 81371)

***Viruses (*Virucidal Activity):**

*Adenovirus Type 2, (ATCC VR-846, Strain Adenoid 6)

*Herpes Simplex Virus Type 2 (ATCC VR-734, Strain G)

*Norovirus, Feline Calicivirus as a Surrogate for

*Adenovirus Type 4, (ATCC VR-4, Strain RI-67)

*Human Coronavirus, (ATCC VR-740, Strain 229E)

*Poliovirus Type 1

*Hepatitis A Virus, (Strain HM-175)

*Human Immunodeficiency Virus (AIDS virus) (HTLV-III_B)

*Respiratory Syncytial Virus (RSV) (ATCC VR-26, Strain Long)

*Hepatitis B Virus (HBV)

*Influenza A Virus, 2009-H1N1 (Novel H1N1), Strain A/Mexico/4108/2009 CDC# 2009712192

*Rhinovirus Type 37, (ATCC VR-1147, Strain 151-1)

*Hepatitis C Virus (HCV)

*Rotavirus, Strain WA

(*Veterinary Viruses:)

*Avian Influenza A Virus, H5N1 (Strain VNHSN1-PR8/CDC-RG, CDC# 2006719965)

*Canine Parvovirus, (ATCC VR-2017, Strain Cornell-780916-80)

*Feline Calicivirus

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Fungi (Fungicidal Activity):

This product is fungicidal when used as directed on hard, nonporous (inanimate) (environmental) surfaces in the presence of a 5% serum load and 1 (one) minute contact time.

Trichophyton mentagrophytes, (ATCC 9533) *Aspergillus niger*, (ATCC 6275)

Yeast:

Candida albicans, (ATCC 10231)

Malodor(s) (Activity) (Counteractancy) – eliminates (destroys) (kills) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors). (Deodorizes by killing microorganisms that cause unpleasant (offensive) odors on hard nonporous surfaces (where odors can develop).) (This product will deodorize hard nonporous surfaces (and places) (in or on) [*insert any of the above listed use sites and/or surfaces*]) (where bacteria growth can cause (obnoxious) (offensive) (malodors)) (where odors can develop).) This product deodorizes areas that are hard to keep fresh smelling.

(See reference sheet for a complete list of claims (and additional directions for use.))

(Emerging Pathogens Claims)

This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Non-enveloped Viruses
- Small, Non-enveloped Viruses

| | |
|---|---|
| <i>For an emerging viral pathogen that is a/an...</i> | <i>...follow the directions for use for the following organisms on the label:</i> |
| Enveloped virus | Feline Calicivirus (ATCC VR-782) |
| Large, non-enveloped virus | Feline Calicivirus (ATCC VR-782) |
| Small, non-enveloped virus | Feline Calicivirus (ATCC VR-782) Canine Parvovirus (ATCC VR-2017) |

Acceptable claim language:

(Avert Sporicidal Disinfectant Cleaner Wipe) (Avert Wipe) (This product) has demonstrated effectiveness against viruses similar to [*insert name of emerging virus*] on hard, non-porous surfaces. Therefore, (Avert Sporicidal Disinfectant Cleaner Wipe) (Avert Wipe) (This product) can be used against [*insert name of emerging virus*] when used in accordance with the directions for use against Feline Calicivirus (ATCC VR-782) or Canine Parvovirus (ATCC VR-2017) on hard, non-porous surfaces. Refer to the (CDC or OIE) website at [*insert pathogen-specific website address*] for additional information.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

[*Insert name of illness / outbreak*] is caused by [*insert name of emerging virus*]. (Avert Sporicidal Disinfectant Cleaner Wipe) (Avert Wipe) (This product) kills similar viruses and therefore can be used against [*insert name of emerging virus*] when used in accordance with the directions for use against Feline Calicivirus (ATCC VR-782) or Canine Parvovirus (ATCC VR-2017) on hard, non-porous surfaces. Refer to the (CDC or OIE) website at [*insert pathogen-specific website address*] for additional information.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

[Optional for appropriate container types:]

[TO PULL WIPES THROUGH LID, SIMPLY...

- 1) Remove lid.
- 2) Remove lid liner from under side of the lid.
- 3) Pull up corner of first wipe from center of roll and push 1 to 2 cm (1/2" to 3/4") through "X" in lid.
- 4) Replace lid.
- 5) Lift lid top and pull up wipes one at a time.

To close between uses to prevent drying, simply keep lid flip top down and ensure wipe corner is inside the raised circle in lid.]

Not for personal cleansing. This is not a baby wipe. Do not flush in toilet.

(Note to Reviewer: For labels that list medical devices as defined by the FDA.)

[This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

Not recommended for use on (or) (avoid contact with): aluminum, brass, chipped enamel, clear plastic, copper, finished floors, natural marble, painted surfaces, and silver.

Note: Prior to use on electronic equipment or components, unplug from electrical outlet, and ensure equipment is powered off.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Special Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with this product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection Procedure: Wipe hard, nonporous inanimate (environmental) surfaces with towelette until thoroughly wet. Surfaces must remain wet for 4 (four) minutes. Wipe surfaces (and let air dry).

For Use as a (One-Step) (Cleaner)/(Disinfectant):

1. Pre-clean heavily soiled areas.
2. Wipe hard, non-porous inanimate (environmental) surfaces with towelette.
3. All surfaces must remain visibly wet for 1 minute.
4. Wipe surfaces (and let air dry).

***Kills HBV, HCV and HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Hepatitis B Virus, Hepatitis C Virus and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

Contact Time: Allow surface to remain wet for 1 minute. For *Clostridium difficile* spores, allow to remain wet for 4 minutes.

Disposal of Infectious Materials: Blood and other body fluids, cleaning materials and clothing must be autoclaved and disposed of according to Federal, state and local regulations for infectious waste disposal.

For Use to Clean and Disinfect Life Science Laboratory Surfaces:

1. Pre-clean heavily soiled areas.
2. Wipe hard, nonporous inanimate (environmental) surfaces with towelette, making sure to wet surfaces thoroughly.
3. Allow the surface to remain wet for 1 (one) minute.
4. Wipe surfaces dry (or) (rinse) (and allow to air dry).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses): For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Wipe hard, non-porous inanimate (environmental) surfaces with towelette.
5. All surfaces must remain visibly wet for 1 minute.
6. Allow to air dry (or rinse (with potable water if necessary)).
7. Ventilate buildings and other closed spaces.
8. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

NOTE: Not for use on handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.

For Use as a Cleaner and/or Deodorizer:

Wipe hard, non-porous environmental surfaces. Allow to air dry (or rinse (with potable water if necessary)).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

STORAGE AND DISPOSAL

Do not contaminate food or feed by storage, disposal, or cleaning of equipment.

STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Keep container tightly closed between uses to retain moisture.

Container Disposal:

NONREFILLABLE CONTAINERS:

Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Nonrefillable container. Do not reuse or refill this container. Dispose of container in trash (or offer for recycling if available).

REFILLABLE CONTAINERS:

Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Refillable container. Refill this container only with this product. Do not reuse this container for any other purpose. Dispose of container in trash (or offer for recycling if available) after final use.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes skin burns and eye damage. Do not get in eyes, on skin, or on clothing. Wear chemical-splash goggles, chemical-resistant gloves and protective footwear. In case of inadequate ventilation wear respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Keep away from clothing and other combustible materials. Mix only with water according to label directions. Mixing this product with chemicals (e.g. ammonia, acids, detergents, etc.) or organic matter (e.g. urine, feces, etc.) may release chlorine gas and other hazardous gases irritating to eyes, lungs, and mucous membranes.

EPA Reg. No. 70627-75

EPA Est. No.

(Lot code letters indicate establishment number.)

[Manufactured][Distributed][by][for]:

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Optional Graphics:



(Note to Agency: Text appearing in parenthesis is done to show optional text.)



(Do not flush symbol from INDA)



REFERENCE SHEET

Avert Sporicidal Disinfectant Cleaner Wipes

(Insert verbatim any Claims statements from the Claims sections from above.)

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

(Insert verbatim any set(s) of Directions for Use from above.)

See the container label for use directions and additional required information for First Aid, Precautionary Statements, and Storage and Disposal.

EPA Reg. No. 70627-75

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